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December 12, 2022

VIA ECF

The Honorable Lorna G. Schofield
 United States District Court
 Southern District of New York
 500 Pearl Street
 New York, NY 10007

Re: Portal Instruments, Inc. v. LEO Pharma A/S, Case No. 1:22-cv-09156-LGS

Dear Judge Schofield:

Pursuant to the Court's Individual Rule III.A.1, we write on behalf of Plaintiff Portal Instruments, Inc. ("Portal") to respond to Defendant LEO Pharma A/S's ("LEO") letter of December 5, 2022, and to respectfully request either that the Court instruct LEO to answer the Complaint so that this matter may swiftly move to judgment on the pleadings, or in the alternative set a more standard briefing schedule than the extended one proposed by LEO. LEO makes three arguments for dismissal, all of which conflict with Portal's allegations, the wording of the Agreement, and New York law.

First, LEO argues the Agreement does not obligate LEO to make any "future installment payment" after terminating development of a product, and that the \$1.5 million Development Payment LEO failed to make constitutes a "future installment payment."¹ This is wrong. LEO's termination became effective 90 days after providing notice to Portal of termination. Termination occurred *after* the Development Payment was due; it is therefore not a "future installment payment" under the terms of the Agreement, and failure to pay constitutes a breach.

Second, LEO argues the Agreement requires that a pharmacokinetic study of Portal's product (the "PK Study") produce a literal statement of bioequivalence to trigger the Milestone Payment. But in fact, the Agreement does not set out a set of "magic words" necessary to convey bioequivalence; it only requires a finding that "bioequivalence criteria" have been met. Portal expressly alleges the PK Study included surrogate findings of bioequivalence and that these findings triggered the Milestone Payment. Whether surrogate findings constitute bioequivalence (they do) is a matter of disputed fact not properly resolved in a motion to dismiss.

Third, LEO argues that Portal's bad faith claims are duplicative of its breach of contract claims. But LEO ignores Portal's allegations that LEO manipulated the PK Study and undertook

¹ Capitalized terms without definitions shall have the meanings given to them by the Agreement and the Complaint.

an unsanctioned post-hoc analysis of the study data, all to pre-arrange its desired outcome. If the Court holds that LEO's failure to make the Milestone Payment is not a breach of contract, that would only be the case because of these bad-faith efforts.

A. The October 2021 Payment Was Not A "Future Installment Payment"

Section 17.2 of the Agreement states that LEO's termination of the development of a product requires "ninety (90) days' prior written notice." While LEO provided notice of its intent to terminate development of Portal's system on September 15, 2021, that termination did not become effective until December 22, 2021. Compl. ¶ 20. LEO's argument that it need not make the October 2021 Payment because it provided *notice* of termination is contradicted by established New York law: "During the period from a notice of termination until the date when [a] termination becomes effective, the contract remains in force and must continue to be performed according to its terms, including making payments at the usual contract rate." *J.C. Studios, LLC v. Telenext Media, Inc.*, 32 Misc. 3d 1211 (N.Y. Sup. Ct. 2011) (internal citation omitted). It is also contradicted by Section 17.6 of the Agreement, which states that "Termination of this Agreement shall not terminate LEO Pharma's obligation to pay all Milestone Payments, royalties and other payments which shall have accrued hereunder." Payment obligations under the Agreement continued to accrue until the Agreement was *terminated*, and were not excused merely by LEO providing notice of its *intent* to terminate.

Reading the Agreement as a whole further makes it clear that "future installment payments" (which is an undefined term) are merely payments that accrue after the Agreement's termination – that is, after the 90-day notice period. *See Allendale Mut. Ins. Co. v. Excess Ins. Co., Ltd.*, 992 F. Supp. 271, 271 (S.D.N.Y. 1997) (parties' intent must be discerned "by reading the contract as a whole, and by considering all its clauses together to determine if and to what extent one may modify, explain or limit another"). Portal does not seek such future payments. Compl. ¶¶ 65-67.

Portal's interpretation of the term "future installment payments" is plainly correct. Even if it were not, though, it is a reasonable interpretation, and "a contract is ambiguous if it contains language that is capable of more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement." *Brass v. Am. Film Techs., Inc.*, 987 F.2d 142, 149 (2d Cir. 1993). Portal's reasonable interpretation of the term "future installment payments" at a minimum renders the Agreement ambiguous, which "creates a question of fact as to the proper interpretation and precludes dismissal before discovery." *Crowley v. VisionMaker, LLC*, 512 F. Supp. 2d 144, 152 (S.D.N.Y. 2007).

B. The PK Study Satisfied the Milestone Payment Criteria

LEO next argues that Portal has failed to state a claim for the Milestone Payment because the PK Study's "surrogate finding" of bioequivalence does not satisfy the milestone requirement. Not so. The Milestone Event requires merely the production of a study report which includes "a statement that the **bioequivalence criteria** have been met." Agreement § 7.3 (emphasis added). It does not, as LEO alleges, state that bioequivalence cannot be proven through surrogate findings (and indeed, the term "bioequivalence criteria" is not defined in the Agreement). *See* LEO Letter at 3 (Dkt. 19); Agreement § 7.3. Portal has alleged that the PK Study's "surrogate finding" of

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bioequivalence triggered the Milestone Event. Compl. ¶¶ 46, 50. At this stage, a court must “accept[] all well-pleaded allegations in the complaint as true, drawing all reasonable inferences in the plaintiff’s favor.” *Int’l Code Council, Inc. v. Upcodes Inc.*, 43 F.4th 46, 53 (2d Cir. 2022) (internal quotation marks omitted). “Thus, [f]act-specific questions cannot be resolved on the pleadings.” *Id.* LEO’s hair-splitting argument that “surrogate findings of bioequivalence” are not the same as “bioequivalence criteria” is a factual dispute, not appropriate for a motion to dismiss.

C. Portal’s Bad Faith Claims Complement Its Breach of Contract Claims

Portal’s bad faith claims complement, rather than duplicate, its breach of contract claims. A bad faith claim is only “duplicative” of a breach of contract claim when “the conduct allegedly violating the implied covenant is also the predicate for breach of covenant of an express provision of the underlying contract.” *ICD Holdings S.A. v. Frankel*, 976 F. Supp. 234, 243-44. Portal alleges that LEO deliberately designed the PK Study, and undertook an unsanctioned post-hoc analysis of the PK Study results, in order to achieve its desired outcome: an outcome where it did not have to make the Milestone Payment. Compl. ¶ 59.

If the Court finds that LEO was not required to make the Milestone Payment, Portal alleges that this was only because of LEO’s decisions to conduct a non-crossover PK Study and apply a post-hoc analysis to the PK Study’s results – breaching the implied covenant of good faith and fair dealing. *Id.* ¶¶ 45, 52. Portal also alleges that LEO breached the implied covenant of good faith and fair dealing when it purported to terminate the Agreement immediately and refused to make the Development Payment due for the 90-day notice period, depriving Portal of compensation while it continued to perform and wind down the project. *Id.* ¶¶ 77-78.

D. LEO Should Answer the Complaint Or Its Motion Should Be Promptly Briefed

As discussed above, LEO’s letter fails to state a viable basis for dismissal of any of Portal’s claims, and the issues in the Complaint are straightforward. LEO should answer the Complaint so that this matter may proceed expeditiously to judgment on the pleadings and resolution. If the Court allows LEO to file a motion to dismiss, LEO’s proposed schedule for briefing these straightforward issues is far too long, particularly when considering LEO has had the Complaint since October 18, 2022, and indeed has been aware of Portal’s demands and the basis for them since December 2021. Portal respectfully requests that LEO’s motion be due no later than January 3, 2023; Portal’s opposition January 20, 2023; and LEO’s reply January 27, 2023. If the Court is inclined to find that Portal did not sufficiently allege the elements for any of its claims, Portal would request leave to amend its Complaint. We thank the Court for its attention to this matter.

Respectfully Submitted,

/s/ Matthew S. Salerno

Matthew S. Salerno

cc: All counsel of record